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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/612,055	07/07/2000	Joseph H. Sklar	SKLAR-21	6809

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[REDACTED] EXAMINER

BUMGARNER, MELBA N

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

3732

DATE MAILED: 08/12/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/612,055	SKLAR, JOSEPH H.	
	Examiner	Art Unit	
	Melba Bumgarner	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 3-13 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 3-8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 4 is objected to because of the following informalities: line 29, "counded" should read —rounded— and line 32, "athat" should read —that--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe a ligament shim having a first pair of opposing arcuate surfaces and/or a second pair of opposing arcuate surfaces, said first and/or second pair of arcuate surfaces each "being provided with a rounded bearing surface being formed at said first end of said body, said first end being positionable at a proximal end of the bone tunnel, adjacent the mouth of the bone tunnel and the at least one ligament, so as to provide a gentle bearing surface for the at least one ligament at the mouth of the bone tunnel, said bearing surface comprising a rounded surface along the first end of said body and extending outwardly and proximally from an inner one of said two walls to an outer one of said two walls, such that the at least one ligament extends adjacent to said rounded surface." (see Response)

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the combination of the ligament shim and at least one ligament is claimed or not. Recitation of "the at least one ligament extends adjacent to said rounded surface" (for example, in claim 3 line 35) positively claims the ligament with an element of the shim.

6. The claims were examined on the merits to the extent as best understood by the examiner in view of the 35 USC 112 rejections made above.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 3, 4 and 5 are rejected as "understood" under 35 U.S.C. 102(b) as being anticipated by Luscombe et al. Luscombe et al. disclose a shim 1 comprising a body having a first end and a second end, a longitudinal axis from the first end to the second end, and at least two walls extending substantially parallel to the axis; at least an outer

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one of the two walls being arc-shaped; a portion of the body defining a cross-sectional area in a plane substantially perpendicular to the axis; and a rounded bearing surface being formed at the first end of the body, the bearing surface comprising a rounded surface along the first end of the body and extending outwardly and proximally from an inner one of the two walls to an outer one of the two walls (figures 1, 5). Patentable weight is not given to the intended use of the shim in the claim. As to claims 4 and 5, the body has a tow hole 5 therethrough between the first end and the second end, the hole extending substantially orthogonal to the axis, and shows a suture¹⁰ inserted through the hole.

9. Claims 6 and 7 are rejected as "understood" under 35 U.S.C. 102(e) as being anticipated by Kim. Kim discloses ligament shim 10 for insertion into a bone tunnel comprising a body having a first end and a second end 12, 14, a longitudinal axis from the first end to the second end and at least two walls extending substantially parallel to the axis; a portion of the body defining a cross-sectional area in a plane substantially perpendicular to the axis; a first pair of opposing arcuate surfaces 19, 20 being formed by the at least two walls, the surfaces curving inwardly toward one another and being formed substantially along the axis, when the shim is positioned between a first portion of the at least one ligament and a second portion of the at least one ligament in the bone tunnel, the shim will conform to the portions and urge the portions against the wall of the tunnel (column 1 line 49), and the first pair of arcuate surfaces each being provided with a rounded bearing surface being formed at the first end of the body, the bearing surface comprising a rounded surface along the first end and extending outwardly and proximally from an inner one of the two walls to the an outer one of the

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two walls, as viewed from the first end being at 12. Patentable weight is not given to the intended use of the shim. Kim shows the first pair of arcuate surfaces each being provided with a rounded bearing surface as best seen in figure 3, if the claim is interpreted from what is shown the disclosure. As to claim 7, Kim shows a second pair of opposing arcuate surfaces, the second pair of surfaces curving outwardly away from one another, formed substantially along the axis, and conforms to the wall of the bone tunnel and the second pair of arcuate surfaces each being provided with a rounded bearing surface being formed at the first end of the body.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim. Kim discloses a ligament shim that shows the limitations as described above; however, does not show the second pair of opposing arcuate surfaces curving inwardly toward one another. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have another pair of opposing arcuate surfaces curving inwardly toward one another, since it has been held that mere duplication of the essential working parts of an article involves only routine skill in the art. Furthermore, the claimed feature is not critical to the claimed invention, since this is an embodiment with the pair of opposing arcuate surfaces as optional to the claimed invention.

Response to Arguments

12. Applicant's arguments filed July 21, 2003 have been fully considered but they are not persuasive. The prior art show the structural limitations of the claims as understood by the examiner. The optional portions shown on figure 14 that is described as outwardly arced to conform to the bone hole are not shown to be at a proximal end of the bone tunnel, adjacent the mouth of the bone tunnel and the at least one ligament, and do not provide bearing surfaces for the at least one ligament.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sherman et al. (6,001,100) is cited to show the state of the art with respect to a fixation implant.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melba Bumgarner whose telephone number is 703-305-0740. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Melba Bumgarner

Melba Bumgarner

Kevin Shaver 8/6/03
KEVIN SHAVER
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